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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,326

04/05/2005

Steffen Hasenzahl

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EXAMINER

WELTER, RACHAEL E

ART UNIT

PAPER NUMBER

4131

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,326	Applicant(s) HASENZAHN ET AL.	
	Examiner RACHAEL E. WELTER	Art Unit 4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☒ Claim(s) 1-5 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/5/05 & 4/5/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Acknowledgments

The Examiner acknowledges receipt of the preliminary amendment filed 4/5/2005 wherein claims 1-5 were amended.

Note: Claims 1-5 are pending.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on October 31, 2002. It is noted, however, that applicant has not filed a certified copy of the 102 50 711.2 application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

The information disclosure statements (IDS) submitted on April 5, 2005 and October 5, 2005 were in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.97. Accordingly, the information disclosure statements were considered by the examiner. A signed copy of forms 1449 are enclosed herewith. In addition, numerous non-patent literature references were submitted but not cited on the 1449. Thus, these references were not considered. ***Specification***

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Objections

The use of the trademarks Aerosil 200, Aerosil R 972, etc have been noted in this application. All trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

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Claim Objections

Claims 1-5 are objected to because of the following informalities. At the beginning of each claim, "formulation" should be singular instead of plural. For example, claim 1 should read "A pharmaceutical and cosmetic formulation..." In addition, the tamped density in claim 1 should include how it was derived as in claim 5 (DIN 55943). By including how the tamped density was derived, no new matter is introduced and claim 1 is still differentiated from claim 5. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Hasenzahl et al, Publication No. 2002/0197311.

The applied reference has common inventors and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-5 are all drawn to a pharmaceutical and cosmetic formulation comprising of hydrophobic highly disperse silicon dioxide with a tamped density of 70-400 g/L. Further limitations to the claims include having a BET surface area between 50 and 400 m²/g (claim 2), 0.01-30 wt.% amount of silicon dioxide (claim 3), and a maximum of 3.0 wt.% of water-wettable contents contained within the silicon dioxide (claims 4-5).

Hasenzahl et al teaches a pharmaceutical and cosmetic formulation containing pyrogenic silicon dioxide with a tamped density of 80-250 g/L, see abstract. In addition, they disclose a BET surface area between 50 and 400 m²/g, see claim 3, and 0.1-10 wt.% of silicon dioxide, see claim 5. The ranges of tamped density, BET surface area, and wt.% are identical or fit within the ranges of those mentioned in claims 1-3.

Although the wt.% of water-wettable contents contained within the silicon dioxide is not specifically taught in Hasenzahl et al, it is inherent that it is the same. Applicant did not explicitly define what is meant by "water-wettable" and only listed a simple method of how it was determined in the specification.

Because the examiner has no access to laboratory equipment, burden is put on the applicant to prove otherwise. In Table 6 on pg. 24 of the Applicant's specification, water-wettable (%) contents are listed with specific tamped densities (within the range of 70-400 g/L) using the prescribed method. Thus, because the tamped densities are within the range specified in Hasenzahl et al, it is reasonable to assume that the prior art's maximum wt% of water-wettable contents is the same.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims refer to "hydrophobic highly disperse silicon dioxide." The specification does not provide a definition for the limitation "highly," which is a relative term. Absent a definition and/or further guidance, this limitation renders the claims indefinite for the following reason:

- a.) The extent of dispersion is unclear (eg. granules, dust).
- b.) An upper/lower boundary for what is acceptably "highly disperse"

cannot be determined.

Thus, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

In addition, claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the term "DIN 55943." Absent a definition and/or further guidance, this limitation renders the claims indefinite for the following reason:

a.) A means by which the density is determined in accordance with the standard is not understood.

b.) The standard could be potentially mutable under different conditions.

Thus, the specification does not provide a standard for ascertaining the term, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached during business hours on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres or Cecilia Tsang can be reached at (571) 272-0867 or (571) 272-0562 respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 4131

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JANET L ANDRES/
Supervisory Patent Examiner, Art Unit 4131

REW